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Research Paper

A randomized controlled trial evaluating inhalation and intravenous anesthesia for laparoscopic cholecystectomy

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ABSTRACT

Background: Propofol and isoflurane have been used as anesthetic drug. Objective: For the purpose of this research, we compared total intravenous (IV) anesthesia (TIVA) with propofol and inhalational anesthesia of isoflurane on hhemodynamic parameters.
Method: This study is a randomized clinical trial, carried out on patients aged 20–40 years; they were randomly divided into two groups. The anesthetics drug administered in both groups were similar. This study comprises of 92 patients undergoing LC. The patients were divided into two groups, forty-six (46) patients received inhaled anesthesia with isoflurane (Group I), and the other forty-six (46) in propofol group (Group P). Hemodynamic variables and depth of anesthesia at various distances were measured and recorded.
Result: In this study, the difference in depth of anesthesia between the two groups over a period of time was statistically significant. Changes in hemodynamic parameters such as HR, SBP and DBP between the two groups was statistically significant over time. Bispectral index in the group receiving isoflurane was statistically lower than those in propofol-based anesthetic treated group ($p = 0.051$).
Conclusion: Propofol and isoflurane are appropriate agent used as a relaxant after general anesthesia for LC. Thus, propofol unlike isoflurane provide less hemodynamic changes, and presented a greater hemodynamic stability.
This clinical trial was carried out in Iran at the center of clinical trial registered with a special registration code: IRCT2015092716516N2.

1. Introduction

The most common intravenous (IV) anesthetic used is propofol, it gives an optimal recovery and short half-life [1]. Propofol is commonly used to induce anesthesia, it is a common choice for sedation in the operating room [2].

Total intravenous anesthesia (TIVA) is a substitute to inhalant anesthesia. It by-pass some shortcomings of inhalant anesthesia, including pollution in the operating room and vaporizer [3]. TIVA with propofol have been widely employed in human outpatient anesthesia [4]. Studies in human showed that recoveries from propofol infusion are as fast as compared to isoflurane or sevoflurane anesthesia, giving rise to a low incidence of postoperative nausea and vomiting (PONV) [5].

Surgical procedures have been transformed slightly by non-invasive surgery [6], and this process have been helpful in anesthesiology [7]. Cholecystectomy is the most common abdominal surgery and usually done under general anesthesia [8,9]. Laparoscopy is a commonly practiced surgical procedures on an outpatient basis and to ill patients [10]. LC is the standard for surgical treatment of gallstone disease [11,12].

Laparoscopy is often performed as an outpatient procedure [13], where the patient will be able to go home the same day after surgery [14]. It may be carried out in a hospital or an outpatient surgical center [15]. Such patients are often placed under general anesthesia for this type of surgery [16]. This means that the patients will sleep through the procedure without feeling any pain [17]. The general anesthesia is achieved through an IV line is inserted in one

This study was approved by the Research Ethics Board of Lorestan University of Medical Sciences.

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of the patients vein. Because this surgery involve lesser pain and it being a gold standard for some operations such as for the treatment of symptomatic gallstones, thus a reason for selecting patients of this surgery [18]. This study compared the methods of using isoflurane inhalation anesthesia and IV anesthesia using propofol in LC. Variable depth of anesthesia and hemodynamic parameters including SBP, DBP and mean blood pressure were evaluated.

2. Materials and methods

This study population consisted of 92 patients who underwent LC aged 20–40 years, referred to (XXX) hospital, ASA physical status was II–IV. Exclusion criteria are; age less than 20 and more than 40 years, patients with any underlying disease including HBP, diabetes, heart and lung problems, allergies to eggs, changes or laparoscopic surgery to open surgery. This study was approved by the Ethical Committee of (XXX) and a written consent was obtained from patients. This clinical trial was carried out in Iran at the center of clinical trial registered with a special registration code: (XXX).

This study is a randomized clinical trial, Patients were randomly assigned to two groups (blocked randomization), 2 cc of 100 mcg IV sufentanil and 2 mg midazolam was administered to the patient. Group P received IV anesthesia, and Group I received inhaled anesthetics, of which 46 patients was assigned to each of group. Then, intubation was performed, patients were continuously monitored for the depth of anesthesia in terms of changes in BP and HR. Hemodynamic instability regarded as SBP lower than 90 mmHg, in spite of volume loading and recurrent using of vasopressors. MAP values were recorded at an interval of 1min when an arterial catheter was used, as it was in about one half the cases; BPs were then recorded oscillometrically at 2–5 min intervals.

The patients undergo mechanical ventilation in order to maintain the concentration of exhaled carbon dioxide at 30–35 mmHg and oxygen saturation at 95%. Bispectral index (BIS) monitoring was employed in all of the patients, with the values of BIS kept at 55. Initial intravenous bolus dosage of 1.5–2 mg/kg propofol was infused. Incremental doses were intermittently administered until the surgery was done. Anesthesia was maintained either with 100 μg propofol infusion using a syringe pump (Infusion Pump, Model AS40A, Baxter, U.S.A.) (TIVA group), or 0.45 MAC isoflurane in oxygen (Isoflurane group). The isoflurane or propofol was discontinued toward the end of the procedure. The BP, HR and depth of anesthesia after induction of anesthesia, after induction of anesthesia, after intubation and every 15 min until the end of the surgery were checked and recorded in a questionnaire. However, all cases were done by the same experienced anesthesiologist, and the doses of the anesthetics applied were comparable to dose used in other studies to achieve a surgical plan of anesthesia based on clinical judgement.

2.1. Statistical analysis

To determine and compare hemodynamic changes and depth of anesthesia in both groups over time, repeated measurement was carried out using ANOVA test. SPSS v25 was used for statistical analysis.

The work has been reported in line with the CONSORT criteria. Moher et al. [19].

3. Results

Our study population consisted of 92 patients who underwent LC. Of the total study population, two patients in Group P and three in Group I withdrew from the study. According to independent *t*-test based on the difference in the average depth of anesthesia as shown in Figs. 1–5, BIS values in the group receiving isoflurane and propofol-based anesthetic treated group before anesthesia were not statistically significant ($p = 0.051$), however, there was a change then after. The difference in mean HR in the group receiving isoflurane and propofol-TIVA treated group before anesthesia were not statistically significant ($p = 0.295$). Based on independent *t*-test, differences in mean SBP ($p = 0.3$), DBP ($p = 0.748$), and mean arterial BP ($p = 0.554$) in the group receiving isoflurane and propofol-TIVA treated group before anesthesia were not statistically significant (Figs. 1–5).

3.1. Depth of anesthesia

Comparison between the depth of anesthesia based on BIS values in the two study groups during different times, due to non-establishment of the symmetry, it suggested that according to test results were not statistically significant ($p < 0.001$) as shown in (Fig. 1). The data from the result was evaluated using Greenhouse-Geisser, according to the results of this study, difference in BIS values over time in each of the groups was statistically significant ($p < 0.001$), but the difference in depth of anesthesia according to BIS values between the two groups was not statistically significant ($p = 0.306$). Interactive effects of time-in the depth of anesthesia based on BIS values were not statistically significant in the sense that the difference in depth between two groups over time was not statistically significant ($p = 0.132$) (Fig. 1).

3.2. Heart rate comparison

In comparing the values of heart rate in both groups during different times, due to non-establishment of the postulated compound, according to test results, were not statistically significant ($p < 0.001$) as shown in (Fig. 2). The data from the result was evaluated using Greenhouse-Geisser, according to the results of this study, variations in measurements of HR over time in each group separately was statistically significant ($p < 0.001$). The differences in HR between the two groups, regardless of the passage time was statistically significant ($p = 0.05$). The interactive effects of time in the HR was statistically significant, the difference in HR between the two groups was statistically significant over time ($p = 0.009$) (Fig. 2).

3.3. Systolic and diastolic blood pressure

In the two study groups during different times, differences in SBP compared to DBP over time in each group separately was statistically significant ($p < 0.001$) as shown in (Fig. 3). Although, the difference in SBP between the two groups was not statistically significant ($p = 0.130$). There was a failure to observe the time change, and averages SBP. The group that received isoflurane shows no significant difference as compared to the group who received propofol. The interactive effects of changes over time in SBP was statistically significant ($p = 0.036$) (Fig. 3).

For DBP, the results from each study groups were statistically significant ($p < 0.001$) as shown in (Fig. 4), but the difference in DBP between the two groups was not statistically significant ($p = 0.419$). There was a failure to observe the time change, and average DBP in the group receiving isoflurane. The interactive effects of time, and DBP group was also statistically significant, difference in mean SBP in the two groups is statistically significant ($p = 0.01$) (Fig. 4).

3.4. Mean arterial pressure

The mean arterial pressure during different times in each group separately is statistically significant ($p < 0.001$) as shown in (Fig. 5).

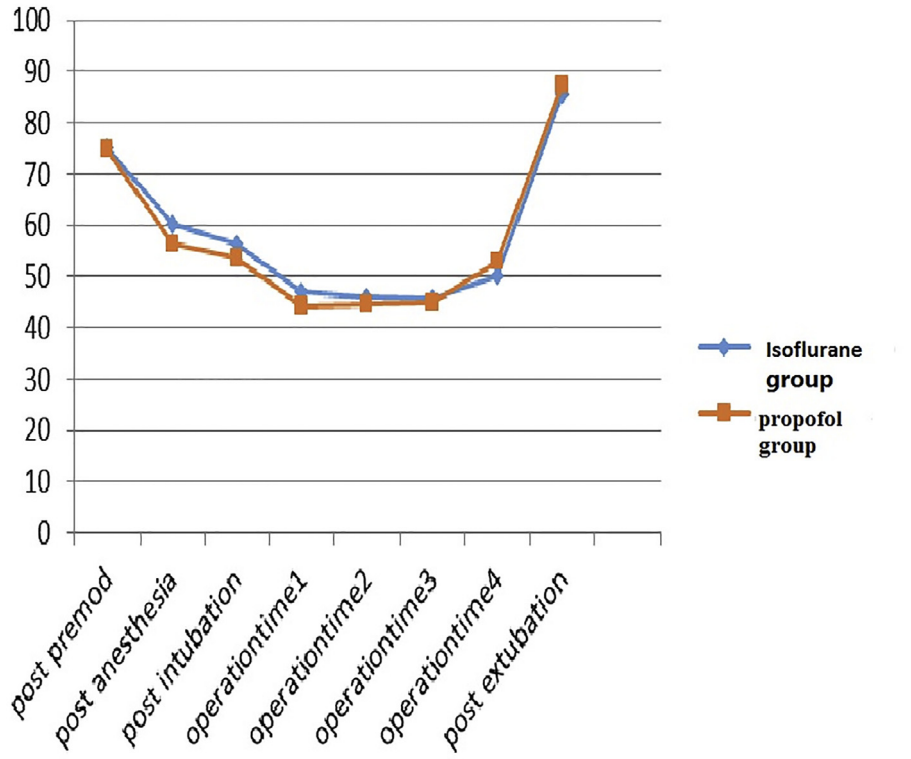

Fig. 1. Comparison of average depth of anesthesia at different time course in the two groups.

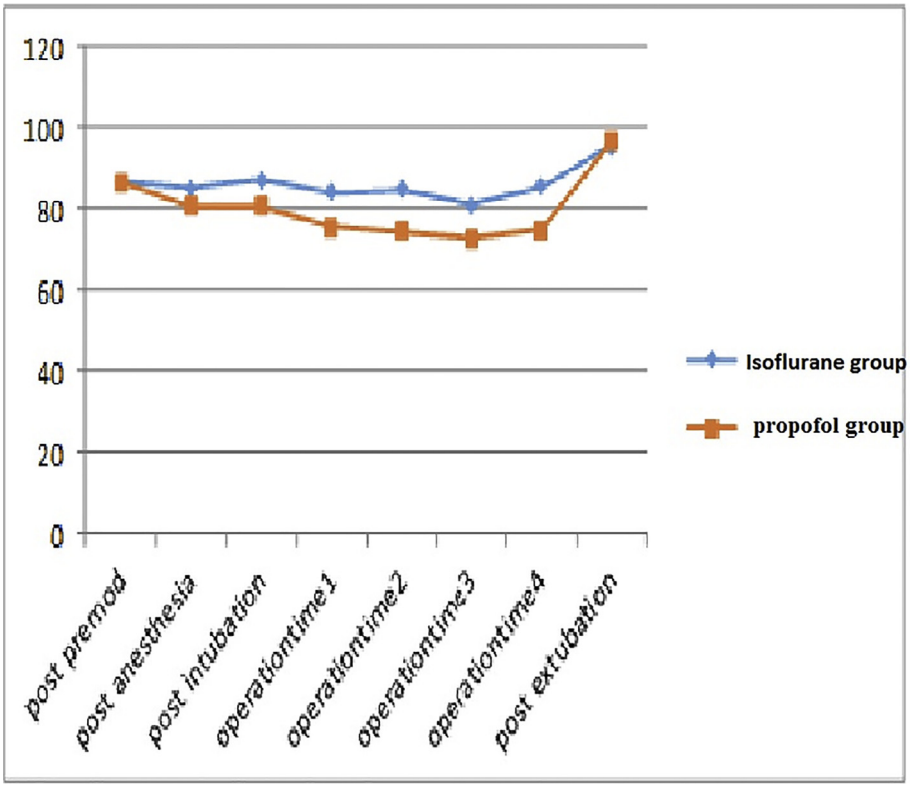

Fig. 2. Comparison of average heart rate at different time course in the two groups.

The difference in mean arterial pressure between the two groups was also statistically significant, regardless of time shift ($p = 0.417$). The mean arterial blood pressure in the group receiving isoflurane was not significantly difference from those that received propofol. The interactive effects of time in the mean arterial pressure was statistically significant in the two groups ($p = 0.004$) (Fig. 5).

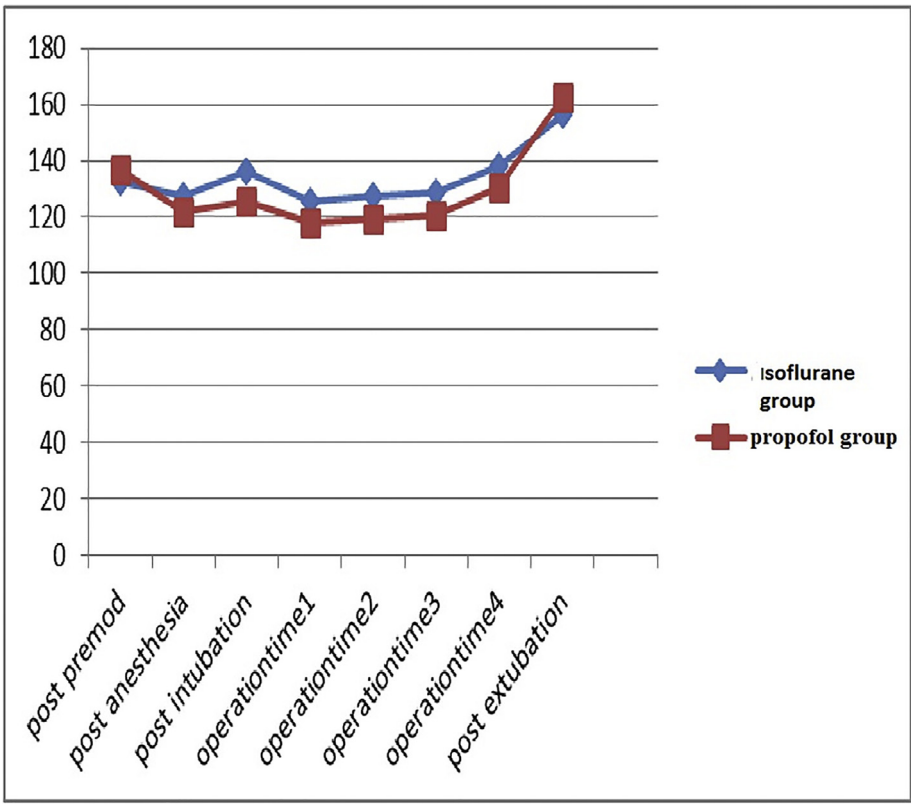

Fig. 3. Comparison of average cystolic blood pressure at different time course in the two groups.

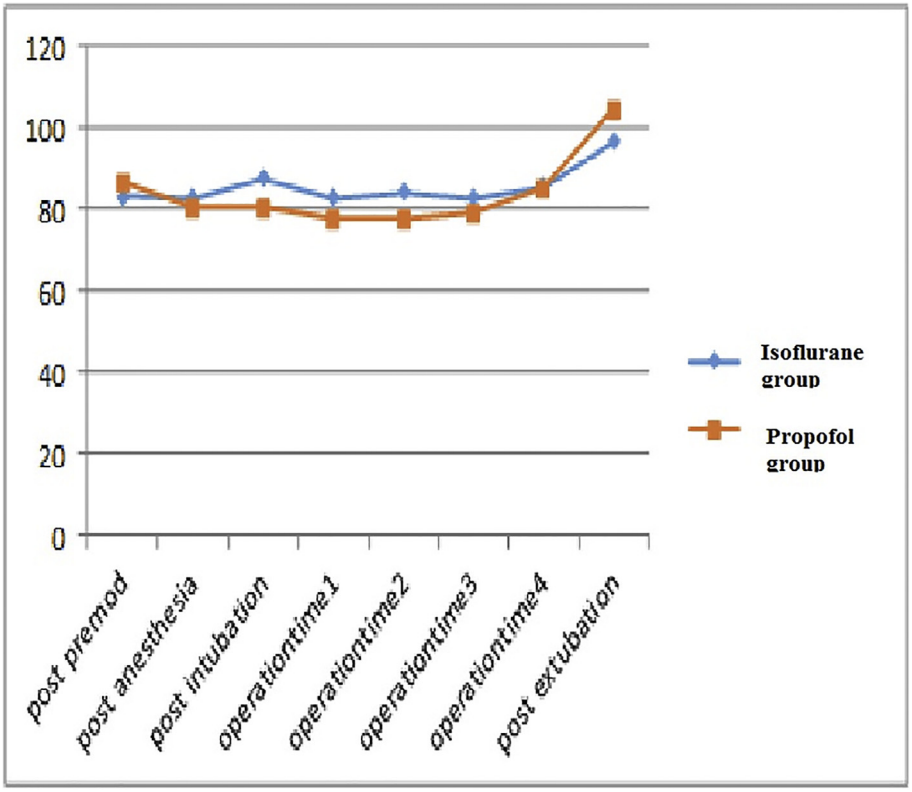

Fig. 4. Comparison of average diastolic blood pressure at different time course in the two groups.

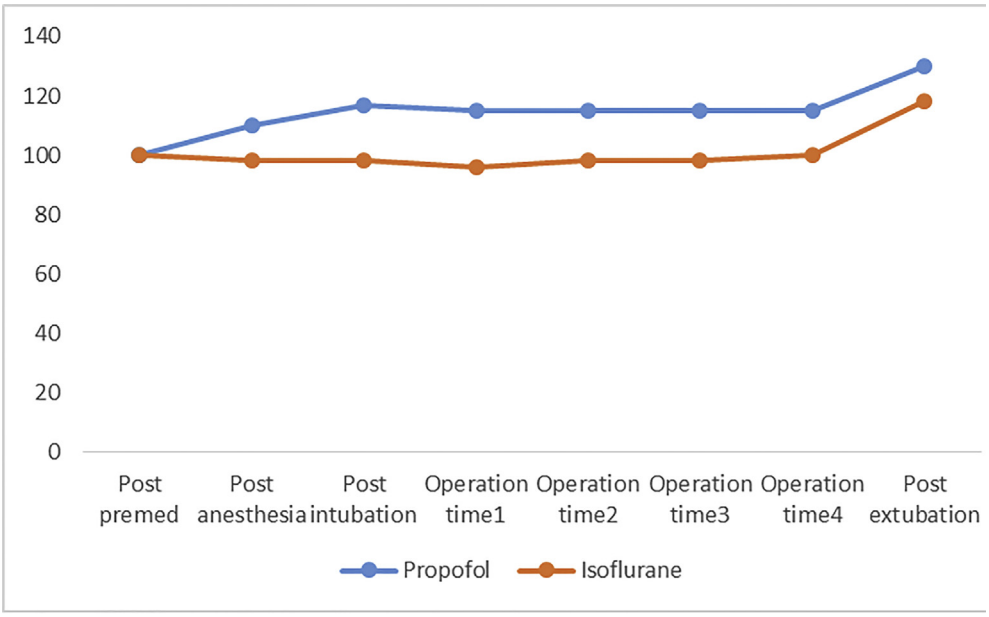

Fig. 5. Comparison of average arterial blood pressure at different time course in the two groups.

4. Discussion

Propofol has been noted as an IV agent least likely to cause PONV in human [20]. General anesthesia frequently used anesthetic for LC because of patient distress related with intraperitoneal CO_2 [2122]. Lately, propofol brings about nausea and vomiting at sub-hypnotic doses [23]. It is the most potent agent for TIVA, since it has a short context-sensitive half-life [24]. However, its weak analgesic characteristics limits its uses as a sole agent, since the dosages needed to remove responses to surgery cause significant cardiopulmonary depression [25].

In this research, propofol-TIVA and isoflurane were used as relaxant during and after general anesthesia for LC since they are well-tolerated by patients undertaking. Early recovery of patients was significantly similar in two groups ($p < 0.0001$). In the present study, no patient showed signs of wakefulness in response to surgical procedures or had postoperative recall of intraoperative events, indicating adequate anesthetic depth during the procedure [26].

For a very short period of time, symptoms of neurologic excitement, during or after the administration of propofol have been noted in humans and dogs [27]. The occurrence of neurologic signs has been variably noted in the past research.

Several studies have been conducted to compare the two methods of inhalation anesthesia. In a study to compare propofol-remifentanil anesthesia with sevoflurane/fentanyl-TIVA during laparoscopic surgery. Hemodynamics parameters, and the side effects of these two methods were compared with each other. In their study, propofol-remifentanil TIVA was appropriate for gynecological surgery, and its major advantage being hemodynamic stability, wake-up time is much shorter, and acceptance of external patients [28]. In another study by Xiaoqian et al. who compared the clinical propofol and remifentanil with sevoflurane in patients who underwent laparoscopic cholecystectomy, there was no significant difference observed between the two studies. Yoo et al. uses TIVA with propofol in laparoscopic cholecystectomy, they reached a conclusion that propofol target control infusion (TCI) causes PONV, which was less in LC. Martorano studied the anesthesia of sufentanil-propofol in comparison with fentanyl-propofol with TIVA for neurosurgery [2]. He came to the conclusion that patients who received sufentanil anesthesia have less need for better cognitive function than those who had received remifentanil [29].

Propofol and remifentanil have also been reported by Epple et al. to be more cost effective than isoflurane/fentanyl, due to reduction in total direct cost profile, users' satisfaction and its better recovery profile [30].

In a study by Marseu and Slinger, they predicted that patients are at risk of peri-operative pulmonary complications intervened to reduce this risk [31]. Anesthesia was maintained with Isoflurane and propofol, they found early recovery was much faster with earlier gain of orientation with propofol anesthesia compared to isoflurane in the early recovery periods [32]. In this study, we estimated depth of inhalation anesthesia of isoflurane and TIVA with propofol on hemodynamic parameters such as BIS, HR, SBP and DBP, depth of anesthesia in LC. When IV and inhalation anesthetics were compared, it was not obvious that the doses used are equi-anesthetic.

Early recovery after propofol-TIVA was as rapid as isoflurane anesthesia in human studies [33]. However, study using dogs as the subject showed that they recovered slower with propofol-TIVA as compared to propofol/isoflurane anesthesia [34]. The slower but smoother early recovery in dogs with propofol-TIVA may be due to physio-pharmacologic properties of the agent and requires more investigation [35]. Vasoactive agents causes tissue hypoxia from vasoconstriction of the splanchnic arterioles, whereas, intraoperative hypotension is related to postoperative death [36]. The hospital stay and mortality rate are increased in patients having a "triple low" of low blood pressure, low BIS, and low MAC concentration of volatile anesthesia [37].

5. Conclusion

With the advent of technology and improving surgical expertise, more prolonged and extensive laparoscopic protocol will be carried out in different patients. Since patients receiving propofol have a higher mean arterial pressure and require less vasoactive agents to treat hypotension, propofol could be beneficial anesthetic agents. We recommend that the perioperative and postoperative hemodynamic effects of propofol as an anesthetic agent should be

further studied particularly in comorbid and hemodynamically unstable patients.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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No funding was secured for this study.

Author contribution

Dr. Sedigheh Nadri: conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr. Arash Karimi and Dr.Farzad Mohammadi: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr.Hormoz Mahmoudvand: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

Conflict of interest statement

The authors deny any conflict of interest in any terms or by any means during the study.

Guarantor

Sedigheh Nadri.

Research registration number

Name of the registry: Lorestan Univesrity of Medical Sciences.

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Hyperlink to the registration (must be publicly accessible): https://en.irct.ir/trial/15432?revision=15432.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Human and animal rights

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

Consent for publication

Informed consent was obtained from each participant.

Availability of data and materials

All relevant data and materials are provided with in manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijso.2020.12.001.

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